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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,765	12/29/2003	Illana Gozes	019856-000210US	8714

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EXAMINER	
WOODWARD, CHERIE MICHELLE	
ART UNIT	**PAPER NUMBER**
1647	

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10/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/748,765	**Applicant(s)** GOZES ET AL.	
	Examiner CHERIE M. WOODWARD	**Art Unit** 1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 September 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *5* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,10-15,17-22 and 26-28*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1646

Continuation of 3. NOTE: Applicant's arguments directed to the written description rejection under 35 USC 112, first paragraph have been considered, but they are not persuasive. Applicant's case law arguments are spurious when the examiner has shown that the genus of ADNF III polypeptides and the genus of ADNF I polypeptides are highly variable in structure (see NCBI references recited in the Office Action of 6 July 2006). In order to comply with the written description requirement, the structure which is asserted to make up the polypeptide must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative embodiment which is adequately described in the specification. The instant disclosure fails to provide an adequate description of a sufficient number of variant ADNF III and ADNF I polypeptides that function to treat MS. The general knowledge and level of those of ordinary skill does not supplement the omitted description because specific, not general, descriptions are needed.

Regarding Applicant's arguments directed to the rejections under 35 USC 103a, have been considered, but they are not persuasive. Applicant's reliance on In re Rijckaert, 28 USPQ2d 1955 (Fed. Cir. 1993) is misplaced. In Rijckaert, the Court relied on In re Oelright, 666 F.2d 578, 581-2, 212 USPQ 323, 326 (CCPA 1981), which held that "[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient [to establish inherency." Additionally, the Rijckaert Court relied on In re Spormann,363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966), which held "[t]hat which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." The Court held that such a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection, citing In re Newell, 891 F.2d 899, 901, 13 USPQ2d 1248, 1250 (Fed.Cir. 1989). The facts, statements, and holdings of the Rijckaert Court factually distinct from the facts of record in the instant case. The examiner has expressly stated of record that the '740 patent and WO 98/35042 teach the administration ADNF peptides as therapeutics to treat neurodegenerative disorders, including Guillan-Barre syndrome, and Brenneman et al., teach the use of ADNF polypeptides to treat conditions related to increased neuronal cell death. As stated in the Office Actions of record, at the time of the invention, there was a recognized problem or need in the art to treat multiple sclerosis. There were a finite number of identified, predictable potential solutions to treat related neurological and autoimmune disorders using an ADNF polypeptide or active core sequence thereof. One of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success because the '740 patent and WO 98/35042 teach the use of ADNF polypeptides and active core sequences thereof for neurological and autoimmune disorders and Brenneman et al., teach the administration of ADNF polypeptides to treat conditions related to increased neuronal cell death. A person of ordinary skill in the art at the time the invention was made would have reasonably known that the ADNF polypeptides and active core sites thereof would have useful in the treatment of neurological disorders, including autoimmune neurological disorders, and would also be useful in the treatment of multiple sclerosis. Moreover, WO 98/35042 teaches that those of skill in the art will appreciate that the list of neurodegenerative disorders is not exhaustive and that ADNF III polypeptides can be used to treat other neurological disorders (page 8, lines 16-18). The teachings of the prior art, as cited by the examiner, are sufficient to permit a person of ordinary skill in the art to recognize the inherent functions of the ADNF polypeptides. Moreover, the teachings of the prior art provide the rationale and motivations to choose from a finite number of identified, predictable solutions, with a reasonable expectation of success (see MPEP 2141(III) Rationale E, also recited as Examination Guidelines for Determining Obviousness under 35 USC 103 in view of the Supreme Court Decision in KSR International Co. v. Teleflex, Inc., as set forth of record).

The submission of the self-serving declaration of a co-inventor under 37 CFR 1.132, where the declarant attempts to demonstrate that the prior art references do not provide motivation for their combination, is not persuasive. The rationale and motivation in the prior art references speak for themselves, as discussed in detail in the rejections of record. Further, Applicant has provided this declaration for the first time in an After-Final submission. There is no showing of good and sufficient reasons why the affidavit was not earlier presented (see 37 CFR 1.116(e)). The declaration is not entered of record.

Regarding Applicant's arguments as to the Double Patenting Rejection, Applicant's arguments have been considered, but they are not persuasive. Applicant argues that a two-way test for obviousness is required over the 11/388,634 ('634) application (now allowed, issued fee paid 10/3/2008). The '634 application has a common inventor and a common assignee with the instant application and claims 1 and 23 of the '634 application are not patentably distinct from instant claims 1, 11, 14, 17, 20, and 21, for the reasons of record. The reference is a pending, but allowed patent application. As such, a one-way test applies. It is noted that Applicant did not pay the issue fee in the '634 case until 10/3/2008, several days after filing the instant After-Final request and that the '634 application has not yet in fact issued as a patent. Arguably, even if the '634 application had previously issued as a patent , a two-way test would still not apply because although the instant application is the earlier filed of the two, Applicant has presented no evidence, showing, or petition decision regarding any adminstrative delay on the part of the Office causing delay in prosecution of the application. Moroever, Applicant has not made a showing or prodvided evidence as to why the conflicting claims could not have been filed in a single application. Both administrative delay on the part of the Office and the showing that the conflicting claims could not have been filed in a single application must be shown in order to apply the two-way test (see MPEP 804).

It is noted that Applicant's arguments (page 15 of 17, first paragraph) states that the pending application claims priority to a provisional application and a PCT application, the national stage of which was filed on 29 December 2003. This is factually incorrect. The instant application only claims benefit under 35 USC 119(e) to US provisional application 60/437650, filed 1/2/2003.

The rejections of record are maintained for the reasons of record and the reasons set forth herein.
/CMW/
AU 1647